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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/717,095	11/22/2000	Aaron I. Vinik	05216.00001	5818

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BANNER & WITCOFF
1001 G STREET N W
SUITE 1100
WASHINGTON, DC 20001

EXAMINER

ROBINSON, HOPE A

ART UNIT PAPER NUMBER

1653

DATE MAILED: 11/26/2001

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/717,095

Applicant(s)
Vinik et al.

Examiner
Hope Robinson

Art Unit
1653



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Aug 16, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5, 7 20) ☐ Other:

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DETAILED ACTION

1. The consent of assignee to the reissue has been received.
2. This reissue application was filed without the required offer to surrender the original patent or, if the original is lost or inaccessible, an affidavit or declaration to that effect. The original patent, or an affidavit or declaration as to loss or inaccessibility of the original patent, must be received before this reissue application can be allowed. See 37 CFR 1.178.
3. The amendment filed March 15, 2001 proposes amendments to the claims that do not comply with 37 CFR 1.173(c). It is noted that applicant instructed the USPTO to add new claims 20-29, however, only claims 20-24 have been filed in the present application. Thus, the amendment does not *per se* comply with 37 CFR 1.173(c) with respect to claims 25-29 which are not present (see for example the comment in 1.173(c) as to "...all added claims...").
4. Applicant is reminded of the continuing obligation under 37 CFR 1.56 to timely apprise the Office of any litigation information, or other prior or concurrent proceeding, involving Patent No. 5,840,531, which is material to patentability of the claims under consideration in this reissue application. This obligation rests with each individual associated with the filing and prosecution of this application for reissue. See MPEP 1404, 1442.01 and 1442.04.

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Oath/Declaration

5. The reissue oath/declaration filed with this application is defective because it fails to identify at least one error which is relied upon to support the reissue application. See 37 CFR 1.17(a)(1) and MPEP 1414. While there is some discussion of the concept of error in the reissue declaration filed with the present application (“the patentee claiming more or less than the patentee had a right to claim in the patent”), this discussion essentially does no more than quote from the rules governing all reissue applications. Such summarization of the rules does not constitute a specific identification of at least one error in the patent (see MPEP 1414, especially page 1400-13, last paragraph, through page 1400-14, first column, first full paragraph). It is noted that applicant submitted an added page which states that “claims are wholly or partly invalid because claim 12 inadvertently reads on a genomic sequence in its natural state”. However, there is no indication that the inventors read and signed off on this added page as it appears at the end of the signature pages. Further it appears that pages are missing from the oath/declaration as the pages read in sequential order: page 1 of 6 (Reissue Application Declaration), page 1 of 6 (Power of Attorney), page 1 of 6 (Declaration/Signatures by Inventors), page 2 of 6 (Signature of Gary Pittenger), page 2 of 6 (Signature of Ronit Rafaeloff-Phail), page 3 of 6 (Signature page), Added Page. Therefore, the oath/declaration does appear to be complete based on the numbering of the page. The information on the added page should be incorporated into the declaration before the signatures appear.

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6. Claims 1-24 are rejected as being based upon a defective reissue Oath/Declaration under 35 U.S.C. 251 as set forth above. See 37 CFR 1.175.

The nature of the defect(s) is in the failure of the Oath/Declaration to clearly set forth what the errors are in the application which is discussed in greater detail above in this Office action.

Information Disclosure Statement

7. The information disclosure statement filed on August 16, 2001 has been considered, however, there are items cited in the 5,840,531 patent to Vinik et al., which have not been cited on the PTO 1449. The following references were missing Hillier et al., 1995 and Hillier et al. 1996. The Hillier references have been cited on the attached PTO-892 (copies not provided on the basis of prior citation to patentee) as they were pulled from the EST database. The Dagron reference appears to incorrectly cited on the face of the US Patent as a GenBank Accession No. Q69201but is actually WO94/15218.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to

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make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-24 are rejected under 35 U.S.C. 112 first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses that the present invention is directed to a preparation of a mammalian protein or polypeptide portions thereof involved in islet cell neogenesis and to provide a DNA molecule encoding a mammalian protein involved in islet cell neogenesis. However, the specification does not clearly set forth how the polypeptide is involved in islet cell neogenesis. Further, the claims recite an isolated DNA molecule encoding a mammalian islet cell neogenesis associated protein (INGAP) and the specific sequence with no limitation to the function of the polypeptide (see claims 1, 12 and 17). In addition, the application only describes an INGAP set forth in SEQ ID NOs: 1 and 2 (DNA and the encoding protein), therefore, the specification fails to describe representative species. Moreover, the claims are directed to portions of the claimed protein (see for example claims 17 and 24), therefore, the claims are drawn to a large variable genus of polypeptides for which the activity has not been described or recited in the claims. Note also that claim 19 is directed to a fragment of the nucleotide sequence and the specification does disclose if these nucleotides encode the claimed protein. Thus, the specification fails to describe other representative species from other sources or by identifying characteristics or structural

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properties other than being an islet neogenesis associated protein (i.e, plays a role in stimulation of islet neogenesis without adequately describing the role). Further, there is no indication in the specification or the claim regarding the amount of variation among species within the genus, structural features that could distinguish compounds in the genus from others in the protein class are missing from the disclosure and no common structural attributes are given that would allow one skilled in the art to identify members of the genus. One skilled in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus and it also fails to give adequate written description.

Therefore, for all these reasons, the specification is not considered to be enabling without undue experimentation, because, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to enable one skilled in the art to be able to practice the invention commensurate in scope with these claims.

9. Claims 17 and 24 are rejected under 35 U.S.C. 251 as being an improper recapture of broadened claimed subject matter surrendered in the application for the patent upon which the present reissue is based. See *Hester Industries, Inc. v. Stein, Inc.*, 142 F.3d 1472, 46 USPQ2d 1641 (Fed. Cir. 1998); *In re Clement*, 131 F.3d 1464, 45 USPQ2d 1161 (Fed. Cir. 1997); *Ball Corp. v. United States*, 729 F.2d 1429, 1436, 221 USPQ 289, 295 (Fed. Cir. 1984). A broadening aspect is present in the reissue which was not present in the application for patent. The record of the application for the patent shows that the broadening aspect (in the reissue)

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relates to subject matter that applicant previously surrendered during the prosecution of the application. Accordingly, the narrow scope of the claims in the patent was not an error within the meaning of 35 U.S.C. 251, and the broader scope surrendered in the application for the patent cannot be recaptured by the filing of the present reissue application. Note that claims 17 with the recitation of "all or a portion of a protein shown in SEQ ID NO: 2" is improper recapture for broadening. Claim 75 in 08/709,662 which corresponds to claim 17 in the present application was amended to put the claims in condition for allowance by inserting the phrase "wherein the gene encodes a protein as shown in SEQ ID NO: 2". Whereas, the present application now amends the same claim to recite "which encodes all or a portion of a protein as shown in SEQ ID No: 2". This attempt to broaden the claims which was rejected in an office action in the parent file above in the re-issue application is a clear example of recapture, which is prohibited. In addition, claim 24 which also recites the language "portion of" also inappropriately broadens the claim.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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10. Claims 1-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because the claim recites “islet cell neogenesis associated **protein** (INGAP) **protein**, wherein the **INGAP protein**”. Note that the recitation of “INGAP” alone is sufficient as it means “islet cell neogenesis protein”. It is suggested that applicant delete the word protein following the acronym (see also claims 2, 15, 16 and 18). Thus, the claim should recite “An isolated DNA molecule encoding a mammalian islet cell neogenesis associated protein (INGAP), wherein INGAP has the amino acid....”. The dependent claims are also included in this rejection.

Claim 5 is indefinite because the claim recites the acronym EBNA without the spelled out meaning.

Claim 8 is indefinite because the claim has inappropriate spacing where it recites “cos7,African”.

Claim 10 is indefinite because the claim recites “the nucleotide probe of claim 9 wherein the sequence encoding ...” and there is no reference to what sequence. The claim should be rewritten as “the nucleotide probe of claim 9 wherein the nucleotide sequence encoding...” (see also claim 13)

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Claim 11 is indefinite because it is not clear what "detectable moiety" the claim is referring to (see also claim 14).

The Basis For Non-Statutory Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thornton*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1-24 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-49 of copending Application No.

09/659,379. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the copending application are directed to a recombinant

construct for expression of INGAP which comprises a nucleotide sequence that encodes the amino acids set forth in SEQ ID NO: 6. Note that the present application is directed to an

isolated DNA molecule which encodes an INGAP protein set forth in SEQ ID NO: 2 and both sequences are identical with the exception of one residue (SEQ ID NO: 6 has an additional

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Methionine in the beginning of the sequence). Furthermore, the present application and copending application both claim probes, primers and have claims directed to antisense strands which would render each other obvious. Although the claims in the two applications are not identical the claimed subject matter in both applications are an obvious variation of each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Art of Record

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Duguid et al. (WO 96/26215, 8/29/96), teach the claimed sequences and an INGAP however, this reference has not been relied upon because of the earlier filing date.

Conclusion

14. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Hope A. Robinson whose telephone number is (703)308-6231. The

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Examiner can normally be reached on Monday and Wednesday- Friday from 9:00 A.M. to 5:30 P.M. (EST).


If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor Christopher S.F. Low, can be reached at (703)308-2932.

Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703)308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-2742. Please affix the Examiner's name on a cover sheet attached to your communication should you choose to fax your response. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

Hope A. Robinson, MS^{HE}

Patent Examiner


CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600